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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,185	11/27/2000	Yvonne Man-yea Chen	P1071P2C2	5661

9157 7590 01/27/2003

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SOUTH SAN FRANCISCO, CA 94080

EXAMINER

ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/27/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/723,185

Applicant(s)

CHEN ET AL.

Examiner

David S Romeo

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-30 and 52-57 is/are pending in the application.
- 4a) Of the above claim(s) 54 and 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-30, 52, 53, 55 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 27-30 and 52-57 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

The preliminary amendments January 17, 2001 (Paper No. 4), February 28, 2002 (Paper No. 6), October 31, 2002 (Paper No. 9), and November 8, 2002 (Paper No. 10) have been entered. Claims 27-30, 52-57 are pending.

Applicant's election of SEQ ID NO: 31 in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Newly submitted claims 54, 57 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the invention originally claimed is directed to a polypeptide wherein Xaa₍₁₁₎ is Nal(1), His, Phe, Trp, Tyr, Pro, Gln, or Met. Newly submitted claims 54, 57 are directed to a polypeptide wherein Xaa₍₁₁₎ is Lys. Newly submitted claims 54, 57 and the invention originally claimed are independent and distinct, wherein neither member of a pair is required for the production or use of the other, and wherein each of the pair can be manufactured independently of the other.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 54, 57 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 27-30, 52, 53, 55, 56 are being examined.

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The application is not fully in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825. Specifically, the number sequences in the paper copy of the sequence listing is 51 whereas the number of sequences in the computer readable form of the sequence listing is 50.

Correction is required.

5

In view of the papers filed February 28, 2002 (Paper No. 5), it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding Iain C.A.F.

10 Robinson and Ross G. Clark as inventors.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

15 A listing of the contents of the present application indicates that a supplemental information disclosure statement (IDS) was filed on March 14, 2002. However, the IDS is missing from the file. Applicants are requested to re-submit the IDS for consideration by the examiner.

20 The subject matter claimed in this application is supported by the disclosure in application serial no. 09/337,227, filed June 22, 1999 but is not supported by any of the other earlier filed applications because the subject matter claimed in this application is not disclosed in

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the manner provided by 35 U.S.C. 112, first paragraph, in the earlier filed applications.

Accordingly, the subject claimed in this application has an effective filing date of June 22, 1999.

Should the applicant disagree, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to June 22, 1999 which

specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to June 22, 1999.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-30, 52, 53, 55, 56 are rejected under 35 U.S.C. 112, first paragraph, as

containing subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make

and/or use the invention. There are no functional limitations to the genus of claimed variant

polypeptides. There is a lack of predictability in the art. Predicting structure, hence function,

from primary amino acid sequence data is extremely complex and there doesn't exist an efficient

algorithm for predicting the structure of a given protein from its amino acid sequence alone. See

Bowie (85, cited by Applicants) page 1306, column 1, full paragraph 1, or Ngo (u11) page 433,

full paragraph 1, and page 492, full paragraph 2. The skilled artisan is left to a substantial

amount of undue experimentation wherein polypeptides meeting the structural limits of the

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claims are randomly made and through trial and error experimentation is left to determine how to use such polypeptides. In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, the unpredictability in the art and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by Artamangkul (v11).

Artamangkul discloses Dyn A-(1-13) cyclic analogues containing disulfide linkages between Cys, D-Cys, Pen (penicillamine), or D-Pen in positions 5 and 13 and cyclization via lactam bridges between D- or L-Orn and Asp to give cyclo[Orn⁵,Asp¹³]Dyn A-(1-13)NH₂ (page 1212, left column, full paragraph 1). Positions 5 and 13 flank an internal sequence of seven amino acids and have side chains covalently bonded to each other to form a locking moiety and thereby constrain the peptide. Dyn A-(1-13) adopts a helical conformation extending from Tyr¹ through Arg⁹ (page 1212, paragraph bridging left and right columns). Accordingly, these cyclic analogues are constrained helical peptides comprising a sequence of nine amino acid residues. HIV gp41 sequence.

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Conclusion

No claims are allowable. SEQ ID NO: 31 is free of the prior art of record.

5 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO
DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH
FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE
10 REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO
THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

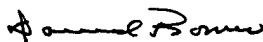
AFTER FINAL (703) 872-9307

15 IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX
NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL
OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

20 ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED
TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



25 DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
JANUARY 24, 2003